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K011151

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SMDA 510(k) SUMMARY

EVIS EXERA Gastrointestinal Videosocpe GIF-Q160Z

A. Submitter's Name, Address, Phone and Fax Numbers

Name & Address of manufacturer: Olympus Optical Co., Ltd.
2-3-1 Shinjuku Monolis Nishi-Shinjuku,
Shinjuku-ku Tokyo, Tokyo 163-0914
Japan

Registration No.: 8010047

Address, Phone and Fax Numbers: 2951 Ishikawa-Cho,
Hachioji-shi, Tokyo 192-8507
Japan
TEL 81- 426-42-2891
FAX 81-426-46-5613

of R&D Division,
Endoscope Group

B. Name of Contact Person

Name: Laura Storms-Tyler

Address, Phone and Fax Numbers: Olympus America Inc.
Two Corporate Center Drive
Melville, New York 11747-3157
TEL: (631) 844-5688
FAX: (631) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Trade Name: EVIS EXERA Gastrointestinal Videosocpe GIF-Q160Z

Common Name: Endoscopic Video Information System

Classification: 21 CFR 876.1500 Endoscope and accessories, Class II

Predicate Device: GIF-Q140 EVIS-140 Series Scope (#K954451)
GIF-1T140 EVIS-140 Series Scope (#K954451)

D. Description of the Device(s)

The subject device is an endoscope which has a zoom magnification function. It is used within the upper digestive tract. The zoom magnification function enables this scope to observe minute lesions and tissue patterns.

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E. Intended Use of the Device(s)

This device has been designed to be used with an Olympus EVIS video system center, light source, equipment, video monitor, Endo-therapy accessories, electrosurgical unit, and other ancillary equipment for endoscopic applications within the upper digestive tract including esophagus, stomach, and duodenum.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate devices, the subject device does not incorporate any significant changes in the intended use, method of operation, material, or design, that could affect safety or efficacy.

Refer to the clinical abstract titled "Magnification Chromoendoscopy for the detection of intestinal metaplasia and dysplasia in Barrett's Esophagus", Dr. Sharma, Dr. Weston, Dr. Sampliner, VA Medical Center, Kansas City, Missouri, July - December 2000.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Olympus Optical Co., Ltd.
c/o Ms. Laura Storms-Tyler
Director, Regulatory Affairs and
Quality Assurance
Olympus America, Inc.
Two Corporate Center Drive
MELVILLE NY 11747-3157

Re: K011151
EVIS EXERA Gastrointestinal Videoscope
GIF-Q160Z
Dated: March 22, 2001
Received: April 16, 2001
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FDS

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

K 011151

510(k) Number(if known): Not assigned yet (K011151)

Device Name: **EVIS EXERA Gastrointestinal Videoscope GIF-Q160Z**

Indications for Use:

This subject device have been designed to be used with an Olympus EVIS video system center, light source, equipment, video monitor, Endo-therapy accessories, electrosurgical unit, and other ancillary equipment for endoscopic applications within the upper digestive tract including esophagus, stomach, and duodenum.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use V OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

David A. Segarra

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K011151

(Optoinal Format 1-2-96)